SCIENTIFIC OPINION



ADOPTED: 29 September 2021 doi: 10.2903/j.efsa.2021.6899

Assessment of the feed additive consisting of sodium benzoate (Protural®) for weaned piglets for the renewal of its authorisation and the extension of use to other growing Suidae (Taminco Finland Oy)

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Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of Protural® (sodium benzoate) when used as a zootechnical additive in feed for weaned piglets and other growing Suidae at 4,000 mg/kg feedingstuff, Protural[®] consists of sodium benzoate without any carrier materials and is currently authorised for use in weaned piglets. This opinion concerns the renewal of the authorisation of Protural® for weaned piglets and the evaluation of the new use in other growing Suidae. The applicant provided evidence that the additive currently in the market complies with the existing conditions of authorisation. The FEEDAP Panel concluded that Protural® is safe under the current conditions of authorisation for the target species, consumers of products from animals fed the additive and the environment. Protural® was not considered as irritant to skin and eyes but a skin sensitiser. Based on dusting potential data, the FEEDAP Panel considered that the powder formulation of the additive represented a risk by inhalation. There was no need for assessing the efficacy of Protural[®] in the context of the renewal of the authorisation for weaned piglets. The efficacy data previously evaluated allowed the FEEDAP Panel to conclude that the additive has the potential to be efficacious at the level of 4,000 mg/kg feedingstuff in other growing Suidae. A conclusion cannot be reached for the efficacy in pigs for fattening.

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Keywords: Protural, sodium benzoate, weaned piglets, other growing Suidae, renewal, extension of use

Requestor: European Commission

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Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgements: The Panel wishes to thank the following for the support provided to this scientific output: Angelica Amaduzzi, Matteo Lorenzo Innocenti, Jordi Ortuño Casanova, Daniel Pagés Plaza.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Fašmon Durjava M, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Anguita M, Galobart J and Pizzo F, 2021. Scientific Opinion on the assessment of the feed additive consisting of sodium benzoate (Protural®) for weaned piglets for the renewal of its authorisation and the extension of use to other growing Suidae (Taminco Finland Oy). EFSA Journal 2021;19(11):6899, 8 pp. https://doi.org/10.2903/j.efsa.2021.6899

ISSN: 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.





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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7. In addition, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from Taminco Finland Oy^2 for renewal of the authorisation of the product Protural[®] (sodium benzoate), when used as a feed additive for weaned piglets (category: zootechnical additive; functional group: other zootechnical additives) and for authorisation when used as feed additive for other growing *Suidae* (category: zootechnical additives; functional group: other zootechnical additives).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive) and under Article 14(1) (renewal of the authorisation). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 12 February 2021.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product Protural[®] (sodium benzoate), when used under the proposed conditions of use (see Section 3.1.1).

1.2. Additional information

EFSA issued one opinion on the safety and efficacy of Protural[®] when used in weaned piglets (EFSA FEEDAP Panel, 2011a) and another opinion on the modification of the terms of the authorisation as regards to the purity of the additive (EFSA FEEDAP Panel, 2011b).

The additive is currently authorised as a zootechnical additive (functional group: other zootechnical additives) for use in weaned piglets (4d5).³

Sodium benzoate (E 211) is also authorised as a food additive in the European Union (EU).⁴

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier 5 in support of the authorisation request for the use of Protural $^{\circledR}$ (sodium benzoate) as a feed additive.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.⁶

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

² Taminco Finland Oy Typpitie 1 90620, Oulu (Finland).

³ Commission Regulation (EC) No 496/2011 of 20 May 2011 concerning the authorisation of sodium benzoate as a feed additive for weaned piglets as a feed additive. OJ L 134, 21.05.2011, p. 6 (Amended by OJ L 34, 5.2.2013, p. 15/Amended by OJ L 314, 11.120.2018, p. 34).

Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives OJ L295, 12.11.2011, p. 177.

⁵ FEED dossier reference: FAD-2020-0040.

⁶ The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2009-0005.pdf



2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Protural[®] (sodium benzoate) is in line with the principles laid down in Regulation (EC) No 429/2008⁷ and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018) and Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

3. Assessment

The additive Protural[®] (sodium benzoate) is currently authorised for use as a zootechnical additive (functional group: other zootechnical additives (improvement of zootechnical performances)) in feed for weaned piglets.

This assessment regards the renewal of the authorisation of Protural[®] (sodium benzoate) when used in feed for weaned piglets, and a new application for its use in feed for other growing Suidae.

3.1. Characterisation

Protural[®] consists of sodium benzoate without any carrier materials. The additive is present on the market in two formulations (granular and powder) and is authorised with a content of sodium benzoate $\geq 99.0\%$. According to the applicant, the manufacturing process and the composition of the additive have not been modified since the previous authorisation.

The applicant submitted analytical results on five batches for each formulation of the product to demonstrate compliance with the authorisation. The analysis showed that the content of sodium benzoate ranged from 99.2% to 99.9% (mean of 99.6%)⁸ for the granular formulation and from 99.9% to 100.3% (mean of 100.1%)⁹ for the powder formulation.

The chemical contamination was analysed in five batches of the additive (granular form) including content of fluoride (< limit of quantification (LOQ)), nitrite (< LOQ), 10 arsenic (< limit of detection (LOD)), heavy metals (mercury, cadmium and lead < LOD) and dioxins (0.2 ng WHO-PCDD/F-TEQ/kg), dioxin-like PCBs (0.06 ng WHO-PCDD/F-PCB-TEQ/kg) and non-dioxin like PCB's (0.47 $\mu g/kg)$. 11 Based on the results, no concern arises on possible presence of impurities in the additive.

Dusting potential, particle size, density and bulk density were measured in three batches of each formulation. Dusting potential (Stauber–Heubach method) ranged from 787 to 919 mg/m³ (mean: 874 mg/m³) and from 197 to 229 mg/m³ (mean: 215 mg/m³) in the powder and granular formulation, respectively. Particle size distribution was measured by laser diffraction. For the powder formulation, around 60% of the particles were above 100 μ m, 20% were between 10 and 100 μ m, 20% were below 10 μ m with no particles below 0.4 μ m. For the granular formulation, the most part of the particles (around 80%) measured more than 600 μ m and no particles were below 1 μ m. Bulk density ranged from 400 to 413 kg/m³ (mean: 405 kg/m³) and from 717 to 740 kg/m³ (mean: 728 kg/m³) in the powder and granular formulation, respectively.

3.1.1. Conditions of use

Protural[®] (sodium benzoate) is currently authorised in feed for weaned piglets as a zootechnical additive at a maximum content of 4,000 mg/kg complete feed.

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Ommission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

⁸ Technical dossier/Section II/Annex_10.

⁹ Technical dossier/Section II/Annex_11.

¹⁰ Technical dossier/Section II/Annex_II_12. Limit of quantification (LOQ) for fluoride and nitrite: 5 mg/kg.

Technical dossier/Section II/Annex_II_13. Limit of detection: arsenic 0.10 mg/kg, mercury 0.05 mg/kg, cadmium 0.05 mg/kg and lead 0.05 mg/kg.

¹² Technical dossier/Section II/Annex_II_17.

¹³ Technical dossier/Section II/Annex_II_14-15.

¹⁴ Technical dossier/Section II/Annex_II_16.



The authorisation, under other provisions, foresees:

- 1) The additive shall not be mixed with other sources of benzoic acid or benzoates.
- 2) Complementary feed containing sodium benzoate may not be fed to piglets as such.
- 3) For piglets (weaned) up to 35 kg.
- 4) Recommended minimum dose 4,000 mg/kg.
- 5) For safety: breathing protection, glasses and gloves shall be used during handling.

The applicant proposes to keep the same conditions of use for weaned piglets. In addition, the applicant requests the authorisation for use of the product in feed for other growing Suidae with the same conditions of use.

3.2. Safety

In its previous assessment (EFSA FEEDAP Panel, 2011a), the FEEDAP Panel concluded that Protural[®] (sodium benzoate) is safe for weaned piglets at the proposed dose of 4,000 mg/kg feed with a margin of safety of approximately three. As benzoates and benzoic acid are rapidly excreted, mainly as hippuric acid in the urine, and no accumulation in tissues occurs, Protural[®] was considered safe for consumers at the recommended use level. Protural[®] was not considered to be irritant to skin and eyes but, in the absence of data, a skin sensitisation potential could not be excluded. Based on particle size analysis, the FEEDAP Panel considered that any exposure to the respiratory system would be limited to the upper respiratory tract. The FEEDAP Panel concluded that the use of Protural[®] in feed for weaned piglets is safe for the environment.

In support of the safety of the additive for the target species and the user, the applicant submitted results of an extensive literature search covering the period from January 2000 to February 2020. The databases searched were CAB Abstracts and Global Health, FSTA (the food science resource) on the Web of Science interface and PubMed. Details of the search strategy and methodology were provided. The applicant retrieved a total of 122 papers, 16 of which were considered relevant (including 4 EFSA opinions). To

No publications providing information relevant to the safety of the target species were identified.

Papers on user safety retrieved from the literature were conflicting. Out of the nine papers found in the literature, three papers (Brasch and Uter, 2011; Schnuch et al., 2011; Schalock et al., 2017) reported a possible skin sensitising effect and five papers, which mentioned or investigated the skin sensitisation effect of sodium benzoate, concluded on the absence of skin sensitisation of sodium benzoate. One paper reported a case of allergic contact dermatitis to sodium benzoate chloracetamide (Sutton and Nixon, 2006); however, the patient tested negative to sodium benzoate alone. Based on the above, the FEEDAP Panel reiterates that the additive should be considered as a potential skin sensitiser. Considering the newly submitted data on dusting potential, the powder formulation of the additive represents a risk by inhalation while for the granular formulation, exposure by inhalation is unlikely.

Considering that (i) benzoates are extensively metabolised into hippuric acid and rapidly excreted in the urine, (ii) no accumulation in tissues is expected to occur and (iii) hippuric acid does not possess a biological activity of concern for the environment (EFSA FEEDAP Panel, 2019), the Panel considers that the use of the additive under the approved conditions of use remains safe for the consumer and the environment.

The Panel also considers that, as the safety for weaned piglets was established in the previous opinion (EFSA FEEDAP Panel, 2011a,b) and no new information has been identified that would lead the Panel to question the outcome of that assessment, the conclusions reached for weaned piglets could be extended to suckling piglets for the period in which solid feed is given, pigs for fattening and extrapolated to all growing Suidae species. With regard to the safety for the consumer, user and environment, the FEEDAP Panel considers that the proposed extension of use would not introduce risks not already considered in the previous assessment and therefore the same conclusions would apply.

¹⁵ Technical dossier/Section III/Annex_III_3.

¹⁶ Technical dossier/Section III/Annex_III_36.

¹⁷ Technical dossier/Section III/Annex_III_4-35.



3.2.1. Conclusions of safety

The FEEDAP Panel considers that the additive remains safe for weaned piglets at 4,000 mg/kg feed and this conclusion can be extended to other growing Suidae.

The Panel concludes that Protural[®] (sodium benzoate) remains safe for the consumers and the environment under the conditions of use currently authorised.

Protural[®] is not considered as irritant to skin and eyes but should be considered a skin sensitiser. The FEEDAP Panel considers that the powder formulation of the additive represents a risk by inhalation while for the granular formulation, exposure by inhalation is unlikely.

3.3. Efficacy

The efficacy of Protural[®] (sodium benzoate) for weaned piglets has been established at 4,000 mg/kg (EFSA FEEDAP Panel, 2011a,b). The conditions of use for weaned piglets have not been modified and therefore no further assessment is needed for the renewal of the authorisation in this species/category.

The applicant has requested to extend the use of the additive at the same use level to other growing Suidae species. No further studies were provided to support the efficacy for pigs for fattening. The conclusions on the efficacy reached in weaned piglets can be extended to suckling piglets for the period in which solid feed is given and extrapolated to minor growing Suidae species at the corresponding physiological stage. Therefore, the Panel concludes that the additive has the potential to be efficacious in minor growing Suidae at 4,000 mg/kg feed.

3.4. Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation and Good Manufacturing Practice.

4. Conclusions

The applicant has provided evidence that the additive currently in the market complies with the existing conditions of authorisation.

The FEEDAP Panel concludes that Protural[®] is safe under the current conditions of authorisation for the target species (weaned piglets and other growing Suidae), consumers of products from animals fed the additive and the environment. Protural[®] is not considered as irritant to skin and eyes but should be considered a skin sensitiser. The FEEDAP Panel considers that the powder formulation of the additive represents a risk by inhalation while for the granular formulation, exposure by inhalation is unlikely.

There is no need for assessing the efficacy of Protural[®] in the context of the renewal of the authorisation for weaned piglets. The FEEDAP Panel concludes that the additive has the potential to be efficacious at the level of 4,000 mg/kg feed in suckling piglets (for the period in which solid feed is given). These conclusions can be extrapolated to minor growing Suidae at the corresponding physiological stage. A conclusion cannot be reached for the efficacy in pigs for fattening.

5. Documentation provided to EFSA/Chronology

Date	Event
05/06/2020	Dossier received by EFSA. Protural [®] (sodium benzoate) for weaned piglets and other growing suidae. Submitted by Taminco Finland Oy.
22/06/2020	Reception mandate from the European Commission
12/02/2021	Application validated by EFSA – Start of the scientific assessment
05/05/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: characterisation and safety for the consumer</i>
17/05/2021	Comments received from Member States
22/06/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
29/09/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

¹⁸ Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.



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Abbreviations

EURL European Union Reference Laboratory

FSTA the food science resource

LOD limit of detection LOQ limit of quantification PCB polychlorinated biphenyls

PCDD/F polychlorinated dibenzo-p-dioxins and dibenzofurans

TEQ toxic equivalent quotient WHO World Health Organization